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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,819	03/08/2004	Vladimir Bakhutashvili	627-B-US	2803

7590 03/28/2006

EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	

Albert Wai-Kit Chan
Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suit 604
141-07 20th Avenue
Whitestone, NY 11357

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/795,819	BAKHUTASHVILI, VLADIMIR	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/05/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on December 21, 2005 has been received and entered into the case. The IDS submissions filed on June 29, September 14 and October 11, 2005 have been received, entered into the case and considered. Claims 2, 23, 24, 65, 67 and 85 – 95 are canceled; claims 99 – 118 are added; claims 99 – 118 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 99 – 118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims a composition, however does not clearly set forth what constitutes the composition. By claiming the composition solely in terms of function and where the composition may be obtained, it is impossible to determine the scope of the claims since the composition is not required to contain any specific component.

Claim 115 is indefinite for not reciting a transitional phrase after "composition", thus the scope of the composition is not clearly set forth.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 99 – 118 are rejected under 35 U.S.C. 102(a) as being anticipated by Drugs of the Future (1999), Bakhutashvili et al. (International J immunorehab 1999), or Pantsulaya et al.

Applicant claims a composition comprising an effective amount of a mixture that modulates apoptosis; wherein the mixture is prepared from amniotic tissue products according to a particular method. Dependent claims are to further limitations of the method by which the mixture is prepared, wherein the composition is characterized by peaks shown in figures 2 or 3.

Drugs of the Future teaches a composition comprising plaferon (abstract, p.974) wherein the composition has anti-proliferative activity (or inhibits/kills cancer cells, or modulates apoptosis) (p.974-975).

Bakhutashvili teaches a composition of plaferon LB, obtained from human amniotic tissues (abstract) which exhibits activities as claimed by applicant (abstract).

Pantsulaya teaches compositions comprising plaferon LB obtained from amniotic membranes, wherein the composition inhibits proliferative activity (or modulates apoptosis) (abstract, p.75). The compositions of plaferon LB have peaks set forth in figures 3, 2, or at least one of peak in figures 3 or 2 (p.77).

Since plaferon is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

5. Claims 99 – 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakhutashvili et al. (Georgian Symposium, 1995).

Applicant claims a composition comprising an effective amount of a mixture that modulates apoptosis; wherein the mixture is prepared from amniotic tissue products according to a particular method. Dependent claims are to further limitations of the method by which the mixture is prepared, wherein the composition is characterized by peaks shown in figures 2 or 3.

Bakhutashvili teaches a composition of plaferon LB, wherein the composition is obtained from a placenta, and has antiproliferative action (or modulates apoptosis) (abstract, p.189).

Since plaferon LB is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant argues that the references do not teach the method by which the product is obtained, the peaks of the instant figures, the amounts of the composition, or interferons.

However, these arguments fail to persuade because as stated above, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. Furthermore, while the reference do not teach the peaks of the figures, such characteristics are considered to be inherent to the compositions. Thus, while the references do not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Regarding the amounts, the references each teach the effect of modulating apoptosis, thus it is assumed that the effective amounts are the same. For these reasons and those stated above, the claims are rejected.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

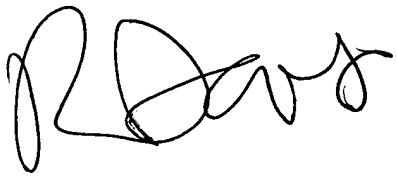
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 16, 2006
AU 1651



RUTH A. DAVIS
PATENT EXAMINER